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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,691	05/26/98	BUKH J	2026-4116US2

HM22/1013

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	7

DATE MAILED: 10/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/084,691	Applicant(s) BUKH ET AL.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1 and 3-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

Claims 1 and 3-59 are pending in this application. Claim 2 has been canceled.

Upon review of the application history, it was determined a new restriction requirement should be set forth that is more in keeping with current practice. The Examiner apologizes for any inconvenience.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 6-10, 17, 20, 47, 48, 50, 51 drawn to polynucleotides, expression vectors, viral vaccine vectors, and methods of producing a recombinant polypeptide, classified in class 435, subclass 69.1, subclass 320.1, class 514, subclass 44.

II. Claims 4, 5, 16, 19, 32, 38, 43, 44, 46, drawn to compositions comprising core polypeptides, and claims 15, 37, drawn to kits comprising those polypeptides and claims 11-14, 33-36, 39-42, and 59 drawn to methods of using those polypeptides to detect antibodies, classified in class 424, subclass 204.1; class 530, subclass 350+; class 435, subclass 5.

III. Claims 21-25, drawn to methods of detecting HCV in a sample using universal primers, and compositions comprising those primers classified in class 435, subclass 6, class 536, subclass 23.1.

IV. Claims 26-32, drawn to methods of determining the genotype of an HCV in a sample, and compositions comprising genotype specific primers classified in class 435, subclass 6, class 536, subclass 23.1.

V. Claims 18, 45, 49, drawn to methods of preventing HCV infection, classified in class 424, subclass 228.1.

VI. Claims 52-58, drawn to core or env antibodies and methods of using them in an immunoassay, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and III/IV are separate and distinct as the polynucleotides encoding the proteins are not suitable for use as primers for PCR, and the primers of inventions III/IV are unable to code for complete proteins. Therefore, searching of these inventions would pose an undue burden upon the examiner if not restricted.

Inventions I and V are separate and distinct as the methods of invention V do not use the polynucleotides of Invention I, and therefore would pose an undue burden upon the examiner if not restricted.

Inventions I and VI are separate and distinct as the polynucleotides are a differing composition of matter than the antibodies of Invention VI. These two differing compositions of matter have differing biological and biochemical properties and differing activities such that is would pose an undue burden upon the examiner to search the unrelated inventions, if not restricted.

Invention II is separate and distinct from Intentions III/IV as the polypeptides of Invention II are not usable in the methods of inventions III/IV. Searches of the polypeptides would not necessarily illuminate methods of performing PCR. As such searching the differing and non-overlapping art areas would pose an undue burden upon the examiner if not restricted.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides can be used to immunoaffinity purify antibodies.

Inventions II and VI are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the antibodies of Invention VI. While the antibodies may bind to the polypeptides of Invention II, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Invention III is separate and distinct from Invention IV as the two inventions are drawn to differing methods. Invention III is drawn to simply detecting the presence of any HCV sequence in a sample, while Invention IV is drawn to detecting a particular genotype of HCV in a sample. The two methods require the use of differing primers, and differing steps such that examining both methods would pose an undue burden upon the examiner if not restricted.

Inventions III/VI are separate from Inventions V and VI as the primers and PCR methods are differing compositions of matter than the peptides or antibodies, and the compositions of one are not useable in the methods of another. As such, search and examination of these substantially non-overlapping inventions would pose an undue burden upon the examiner if not restricted.

Inventions V and VI are separate and distinct as the methods of preventing infection using a peptide vaccine are differing methods from the peptide detecting methods using antibodies, and the antibody compositions themselves are not usable in the methods of preventing infection. Therefore, searches of both substantially non-overlapping art areas would pose an undue burden upon the examiner if not restricted.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: Each polypeptide Sequence of 52-102 or 155-206, and each polynucleotide encoding each polypeptide sequence is a patentably distinct sequence. SEQ ID

NO 52-102 are env polypeptide sequences, and SEQ ID NO: 155-206 are core polypeptides. If Groups I, V or VI is elected, the following elections are also required:

Applicant must select from either a) env sequences or b) core sequences.

Within a) or b), a further species must also be selected. (For example, If Group I is elected, and core sequences are elected, then a single polynucleotide sequence encoding a core sequence should also be elected.)

If Invention II is elected, the following species elections are required:

Applicant must elect either a) env sequences or b) core sequences

Further Applicant must elect i) universal peptide sequences or ii) genotype specific peptide sequences

And finally, one single polypeptide sequence of either a universal peptide sequence or genotype specific sequence must be chosen. (For example, the election could be, Group II, core universal polypeptides, SEQ ID NO: x)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 4 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Due to the complexity of the restriction requirement, no telephone election was attempted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

Mary Zeman
Examiner, 1631

mkz
October 11, 2000